

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

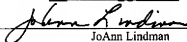
Application No.:	10/659,490	Confirmation No.:	3452
Applicant :	Robert B. DeVries		
Filed :	September 10, 2003		
TC/A.U. :	3731		
Examiner :	Lang, Amy T.		
Title :	COMPOSITE MEDICAL DEVICES		
Docket No. :	1001.1602101		
Customer No. :	11050		

**REPLY BRIEF**

Mail Stop Appeal Brief - Patents  
Assistant Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

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By \_\_\_\_\_

  
JoAnn Lindman

Dear Sirs:

Pursuant to 37 C.F.R. § 41.41, Appellant hereby submits this Reply Brief in furtherance of the Notice of Appeal filed on March 24, 2010, the Notice of Panel Decision from Pre-Appeal Review dated mailed June 8, 2010, the Appeal Brief filed on July 6, 2010, and the Examiner's Answer mailed February 29, 2010. Appellants authorize the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of \$540 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

### **REPLY TO EXAMINER'S ANSWER**

A. With regard to the 35 U.S.C. §112, second paragraph rejection of claim 67, the Examiner has failed to clarify that rejection in response to Appellants' communication after the Final Office Action. The Examiner incorrectly quoted claim 66 in the rejection of claim 67. Further, it is believed that the amendment of claim 67 and the discussion in the communication of January 26, 2010 removed any ambiguity regarding the designation of a first direction. The lack of further discussion has been interpreted as acceptance of the amendment. The restatement of the rejection in the Examiner's Answer apparently indicates that the issue is being raised again, but again incorrectly quotes claim 66. Appellants believe that the rejection has been rendered moot by the amendment and respectfully request that the rejection be overruled.

B. With regard to the Examiner's assertion, bridging pages 8 and 9 of the Examiner's Answer, that the inner Nitinol member of Tomonto "is surrounded by the outer stainless steel member along at least two sides", Appellants are unclear how a layer adjacent to one side of a second layer may surround the second layer along at least two sides. Appellants further note that the Examiner has relied upon an incorrect definition of the term "surround" after acknowledging Applicants' definition and has asserted in the Advisory Action:

"it is the Examiner's position that to surround or encase may not limit to a complete enclosure. Surround is also defined as to enclose and enclose is defined as to hold in (Merriam-Webster)"

Although the Examiner has asserted that the Merriam-Webster dictionary defines "surround" as "to enclose", the Examiner has erred in selectively quoting only a portion of the definition:

#### Definition of SURROUND

1 a (1) : to enclose on all sides : envelop <the crowd surrounded her> (2) : to enclose so as to cut off communication or retreat  
(Merriam-Webster's Online Dictionary, 11th Edition, October 21, 2010)  
(Emphasis added.)

# Definition of ENCLOSE

1 a (1) : to close in : surround <enclose a porch with glass> (2) : to fence off (common land) for individual use b : to hold in  
(Merriam-Webster's Online Dictionary, 11th Edition, October 21, 2010.)

The common and ordinary meaning of "surround" is further confirmed:

surround:

verb: extend on all sides of simultaneously; encircle ("The forest surrounds my property")

(<http://www.onelook.com>, October 21, 2010, a summary of 37 dictionaries with English definitions that include the word surround.)

enclose:

verb: close in or confine

verb: surround completely ("Darkness enclosed him")

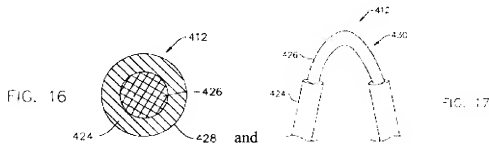
verb: introduce

verb: enclose or enfold completely with or as if with a covering

(<http://www.onelook.com>, October 21, 2010, a summary of 29 dictionaries with English definitions that include the word enclose.)

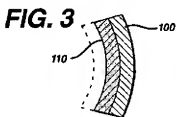
If extrinsic reference sources, such as dictionaries, evidence more than one definition for the term, the intrinsic record must be consulted to identify which of the different possible definitions is most consistent with applicant's use of the terms. Brookhill-Wilk 1, 334 F. 3d at 1300, 67 USPQ2d at 1137; see also *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998) ("Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings.")

Examination of the text and figures of the pending application will indicate that the term "surround" is used in its common and ordinary meaning of to "extend on all sides of simultaneously; encircle" to describe an inner core member surrounded by an outer member as for example in:



The usage of “surround” is discussed and illustrated more extensively in the Appeal Brief. It is believed that the Examiner initially may have been misled by figures which illustrate longitudinal cross-sections of the wire. The Examiner has not cited an authority which would support the use of the term “surround” to describe the situation in which the central layer of a sandwich structure comprising three distinct and generally parallel layers would be construed to provide a center layer “surrounded” by either the outermost layer or the innermost layer.

The Examiner errs in departing from the teaching of Tomonto, that the stent structure described at the cited col. 4, lines 50-56 optionally could comprise three layers, by turning to an assertion that the distinct innermost and outermost stainless steel layers, free of any continuous connection at any time, may be considered together as a entity which may be referred to in the singular. Contrary to the Examiner’s assertion, the outer member of the layered structure of Tomonto contacts the central layer of the optional sandwich structure of Tomonto along a single side of an open cylindrical shell surface and thus fails to “surround” the central layer portion of a strut cut from the three-layered cylindrical blank. The optional structure described by Tomonto would resemble modified Fig. 3 below (in which the third and innermost layer is represented by broken lines and the Examiner’s statement that inner layer 110 “is surrounded by the outer stainless steel member [100] along at least two sides” is clearly in error.



The Examiner’s reference, in the Examiner’s Answer, to page 3 of the final Office Action disclaims an alternative, but also incorrect, interpretation in which the outer cylindrical shell 100 of the tube from which the stent is to be cut may be said to surround the inner cylindrical shell 110 of Tomonto. Claim 1 recites: “wherein said first composite elongated member has a solid cross-section”.

The Examiner further argues that that the Appellants do not show complete enclosure of the inner core by an outer member after the flexibility regions are formed.

Appellants respectfully disagree. An inner core member 426 surrounded by an outer member 424 is illustrated in Fig. 17 above as well as in Figs. 8, 10, and 15. An outer member surrounding a core member also is illustrated in cross-sectional presentations which would be readily understood by one of ordinary skill in the art in Figs. 3, 4, 6, 7, 9, and 11-16. The Examiner's Answer acknowledges that "the outer member surrounds the inner member along its length" at page 10.

The plain language of the claims, as represented by independent claim 1, recites that the composite medical device includes "at least one flexibility region formed on said first composite elongated member formed by selectively removing a portion of the outer member to expose the inner member". The Examiner's interpretation of Fig. 17 would appear to require that the claimed flexibility region 430 of Fig. 17 not be present at any point along the composite member which would render the claim meaningless. The Examiner's position that "there is a distinction between to surround and to completely surround" is immaterial in that the pending specification only uses the term "surround" and does so consistently in a context which would be consistent with the common and ordinary meaning of the word. As noted above, the definition which governs claim interpretation is the definition most consistent with applicant's use of the terms.

Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement. (MPEP 2173.02) (Emphasis added.)

It should be further noted that the definition of "enclose" upon which the Examiner relies for modification of the direct definition of "surround" includes "surround completely" and to "enclose or enfold completely with or as if with a covering". Accordingly, the definitions relied upon by the Examiner appear to define "surround" as encompassing "surround completely".

The Examiner's further reference to a "sandwich" again erroneously posits that one of the outer slices of bread, not apparently connected to a second innermost slice of bread, may (but does not inherently) "surround" the contents of a sandwich of which it is an element, but fails to account for the ready ability of the contents, such as mayonnaise,

catsup, or other filling, to fall out of the sandwich at the perimeter, and thus not be “held in” or “surrounded. Appellants congratulate the Examiner if this has not happened to her. Appellants repeat the earlier assertion that the proper standard with respect to determining the meaning of “surround” to be applied to the claim is the patent disclosure in which “surround” is used in the sense of “to enclose on all sides” subject to the requirement that the device also includes at least one flexibility region formed by selectively removing a portion of the outer member.

Appellants appreciate the Examiner’s colorful fence analogy, but suggest that the Examiner’s description of a fence in which the fencing material is discontinuous at the posts is not reflective of common fence construction and further suggest that the Examiner may not have tried to walk through the fencing “surrounding” a piece of property. It is believed that a fence “surrounding” a piece of property as the term is used in the pending application would adequately contain or exclude the Examiner despite the porosity provided by the holes in the fencing material.

C. The Examiner has focused significant attention on the relative elasticity of Nitinol vs. stainless steel. Independent claim 1 does not specify either Nitinol or stainless steel, but rather recites only:

“a first composite elongated member formed from an outer member comprising a first material and an inner member comprising a second material different from the first material, the outer member surrounding and encasing the inner member, wherein the second material is more elastic than the first material”

Tomanto teaches generally that that a stent may be formed from a plastically deformable layer adjacent to a superelastic layer. This in no way precludes the modulus of elasticity, or any other measure of elasticity, of the superelastic material being greater than the elasticity of the plastically deformable material. Indeed, the commonly employed superelastic materials are plastically deformable with Nitinol having an elastic limit generally in the 3% to 8% strain range (see, for example, U.S. Patent No. 6,422,010) and thus a single superelastic material may provide both a plastically deformable material and a superelastic material – Tomonto does not teach or claim that the materials are

different. Further, Tomanto explicitly teaches that Nitinol is a material which plastically deforms and thus appears to teach that Nitinol is suitable as the outer layer:

“The martensitic metal first deforms elastically upon the application of additional stress and then plastically with permanent residual deformation.” (Col. 2, lines 49-51.)

The disclosure of Tomanto is limited to a plastically deformable layer adjacent to a superelastic layer, with an example being provided in which the plastically deformable layer is stainless steel and the adjacent, but not surrounded, superelastic layer is Nitinol. The disclosure of Tomanto with respect to the use of those materials in an example of a layered stent is insufficient to overcome the structural deficiencies of Tomanto, as applied to the pending independent claim, as discussed in greater detail above and in the Appeal Brief.

*Per se*, elasticity is the property of returning to an initial form of state following deformation. Accordingly, a Nitinol sample subjected to, say a 10% strain, will not return to its initial form or state and would not be considered to be elastic, but rather has been plastically deformed.

The pending claim does recite a relationship between the elasticity of the first and second materials which relationship is in addition to the structural features required by that claim. The mere existence of pairs of materials which share that relationship within a reference does not render the pending claim obvious unless the relationship is inherently present in the disclosure and accompanied by a structure meeting the remaining limitations of the claim. As discussed above and in the Appeal Brief, the structure of Tomanto does not meet the structural limitation of an outer member surrounding and encasing the inner member as that limitation would be understood by one of ordinary skill in the art.

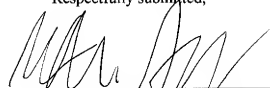
#### D. CONCLUSION.

For the reasons stated above and in the Appeal Brief, claims 1-4, 6-10, and 65-69 are not anticipated by Tomanto; claim 5 is nonobvious over Tomanto in view of Moore; and the Examiner's rejections of claims 1-10 and 65-69 under 35 U.S.C § 102 and § 103 should be overruled.

Date:

Nov. 23, 2010

Respectfully submitted,



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